IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SCIELE PHARMA, INC. and SCIELE PHARMA CAYMAN LTD., Plaintiffs, v. MYLAN PHARMACEUTICALS, INC. and MYLAN LABORATORIES, INC., Defendants.	C.A. No. 07-664-GMS REDACTED

PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS PLAINTIFFS' COMPLAINT FOR LACK OF STANDING AND SUBJECT MATTER JURISDICTION

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I. NATURE AND STAGE OF PROCEEDINGS

On October 22, 2007, Sciele filed this suit against Mylan for infringement of the '741 Patent under 35 U.S.C. § 271(e)(2). [D.I. 1.] Mylan answered, replied and filed a Motion to Dismiss on December 18, 2007. [D.I. 11, 12.]

II. INTRODUCTION AND SUMMARY OF THE ARGUMENT

Simply put, Mylan has jumped the gun. Before filing its Motion to Dismiss, Mylan failed to ensure that the information on which it based its arguments was current or accurate. As a consequence, Mylan's motion relies on an outdated 2001 agreement that has been superseded in relevant parts by two additional agreements between Sciele and Bayer.

Together, these newer agreements grant to Sciele the necessary rights in U.S. Patent No. 4,892,741 ("the '741 Patent") to sue Mylan in Sciele's name alone. In fact, the intent of the most recent agreement, dated October 18, 2007, could not be more clear—the parties specifically designed that agreement to ensure that Sciele possessed the rights required to enforce the '741 Patent in its own name, without having to join Bayer.

Under Federal Circuit precedent, the rights granted to Sciele last fall and in 2004 constitute all substantial rights in the '741 Patent and demonstrate that Sciele is the proper, solitary plaintiff in this case. Consequently, Mylan's motion to dismiss should be denied.

In the alternative, but only if the Court determines that Sciele alone does not have standing to sue on its own, Sciele and Bayer together unquestionably have that right. Accordingly, if the Court finds that Sciele does not possess all substantial rights, the appropriate

remedy here is not an outright dismissal but rather the joining of Bayer as a co-plaintiff. Such a joinder would preserve the status quo under the Hatch-Waxman Act, while causing no prejudice to Mylan. If necessary, Bayer has consented to this joinder. A proposed amended complaint is attached to this opposition, along with a motion for leave to amend.

III. BACKGROUND

A. This Case is Governed by the Hatch-Waxman Act, the Compromise Statute Between the Interests of Pioneer and Generic Drug Manufacturers

This case, as well as the related case pending before this Court, *Sciele Pharma, Inc. v. Mylan Pharmaceuticals, Inc.*, 07-818 (GMS), arises under the Hatch-Waxman Act. *See* 35 U.S.C. § 271(e)(1). The Hatch-Waxman Act makes the filing of an abbreviated new drug application ("ANDA") for a proposed generic drug an act of infringement, allowing the pioneer company to sue for infringement when the ANDA is filed instead of being forced to wait until the generic company actually sells its product, at which point the damage to the market of the pioneer product would already be done. *See* 35 U.S.C. § 271(e)(2).

To identify the patents that cover particular approved drugs, the Hatch-Waxman Act requires holders of approved New Drug Applications (NDAs) like Sciele's Sular® to submit relevant patents to the FDA that are then published in FDA's so-called "Orange Book." 21 U.S.C. § 355(b)(1)(F). In turn, if a generic company wishes to market the drug before the expiration of any of the patents listed in the Orange Book, the generic company must file a "Paragraph IV certification" with the FDA upon filing its ANDA, certifying that those patents are invalid or will not be infringed by the manufacture, use, or sale of the drug that is the subject of the ANDA. 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

The generic company must also notify the NDA holder of the Paragraph IV certification. 21 C.F.R. § 314.95(c)(6). This notice is referred to as a "Paragraph IV letter" and is intended to

provide sufficient information about the proposed generic version for the NDA holder to determine if the generic product infringes any of the patents listed in the Orange Book. *Id.*

After receiving the Paragraph IV letter, the Act provides just 45 days for the pioneer companies to bring suit in order to preserve its rights under the Act. *See* U.S.C. § 271(j)(5)(B)(iii). If the pioneer company brings suit within that period, the FDA cannot approve the generic company's ANDA for up to 30 months or until the occurrence of certain events. *Id.* This statutory stay affords pioneer companies time to seek relief in court without having to worry about the generic company selling its infringing copy of the pioneer drug in the meantime, thereby destroying the market for the pioneer drug.

B. Sciele's Sular® Product

Sciele is the holder of NDA No. 20-356 for Sular®, an extended release pharmaceutical tablet for treating high blood pressure, also known as hypertension. Lowering high blood pressure can prevent many serious medical conditions such as strokes, heart attacks, and kidney problems. By all accounts, Sular® is a commercially successful product. Last year alone, U.S. physicians wrote over one million prescriptions for Sular®.

The active ingredient in Sular® is nisoldipine, which works by relaxing blood vessels to allow blood to flow more easily and thereby reduce blood pressure. NDA No. 20-356 covers four different dosages of Sular®—10mg, 20mg, 30mg, and 40mg—all of which are able to be dosed just once daily because of the drug's extended release properties.

The Sular® formulation is covered by the claims of the '741 Patent. Under the relevant statutory and regulatory requirements, Sciele therefore listed the '741 Patent in the Orange Book as related to Sular®.

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C. The Licensing Agreements Between Sciele and Bayer

The '741 Patent issued on June 8, 1988 to the then-assignee Bayer Aktiengesellschaft ("Bayer AG"). Bayer AG later assigned the patent to Bayer Healthcare Aktiengesellschaft ("Bayer Healthcare AG"). In a series of agreements beginning in 2001, Bayer AG and Bayer Healthcare AG exclusively licensed the '741 Patent to Sciele, granting Sciele all rights necessary to bring this lawsuit. These rights include

1. The 2001 Original Agreement

On December 12, 2001, Bayer AG entered into a Distributorship Agreement ("2001 Agreement") with Sciele, known at the time as First Horizon Pharmaceutical Corp., in which it licensed Sciele certain rights in the '741 Patent and appointed Sciele as the exclusive seller and distributor of Sular® in the United States. [D.I. 14, Ex. D, Section 2.1.] This is the agreement on which Mylan wrongly relies. Because it has been superseded in relevant part by later agreements,[1] the 2001 Agreement argued by Mylan is of little, if any, relevance to the issue of standing.

2. The 2004 New Agreement

On October 1, 2004, Bayer Healthcare AG ("Bayer"), which had assumed Bayer AG's healthcare business, entered into a new agreement with Sciele.[2] In this Agreement, known as the

[1] The later agreements—one from 2004 and one from 2007—that supersede the 2001 Agreement were both entered into before Sciele filed this lawsuit.

[2] The 2004 Agreement is between Bayer Healthcare AG, First Horizon Pharmaceutical Corp., and First Horizon Pharmaceutical Cayman, Ltd. First Horizon Pharmaceutical Corp. and First Horizon Pharmaceutical Cayman, Ltd. are now known as Sciele Pharma, Inc. and Sciele Pharma Cayman, Ltd.

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New Distributorship Agreement ("2004 Agreement"),

[Marsden Decl., Ex. A, 2004 Agreement at 1.] [3]

[Ex. A, 2004 Agreement, Section 2.2.]

In addition to granting these "exclusive" rights to Sciele,

[Ex. A, 2004 Agreement, Section 2.1

Accordingly, Sciele's rights under the 2004 Agreement are "exclusive" not just in name, but in actual effect.

[3] All exhibit citations refer to the accompanying Declaration of William J. Marsden, Jr. unless otherwise noted.

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Ex. A, 2004 Agreement, Section 2.1.]

[*Id.* at Section 2.2. (emphasis added.)]

The 2004 Agreement also addresses the respective rights of Bayer and Sciele to sue for infringement in a very different manner than the 2001 Agreement.

[4]

[2004 Agreement, Section 16.3.]

[*Id.*]

[*Id.*]

[*Id.*]

3. The 2007 Amended Agreement

While the 2004 Agreement grants to Sciele many exclusive rights under the '741 Patent, on October 18, 2007, Bayer and Sciele amended the 2004 Agreement ("2007 Agreement"),

[5] [Marsden Decl., Ex. B, 2007

[4] Because the products at issue are pharmaceutical preparations, the only way a potentially infringing nisoldipine product could be marketed would be through the FDA approval process, under which Paragraph IV letters are required.

[5] The 2007 Agreement states that the parties are amending the Amendment and Services Agreement. The Amendment and Services Agreement, entered into on January 23, 2007, amends several agreements between the parties, including the 2004 Agreement.

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Agreement at C.]

[*Id.* at B.]

In so doing, the 2007 Agreement makes at least two points very clear.

[Ex. B, 2007 Agreement, Section 2.9 (emphasis added).]

Second,

[2007 Agreement, Section 2.9.]

D. Mylan's ANDAs for Generic Versions of Sular®

On September 10, 2007, Sciele received a Paragraph IV letter from Mylan in which Mylan informed Sciele that it had filed ANDA No. 79-051 seeking FDA approval to manufacture and sell a generic copy of Sciele's Sular® tablets in the 40mg dosage. The Paragraph IV letter alleged that Mylan's generic version of Sular® would not infringe the '741 Patent but, contrary to the statute, gave very limited information about Mylan's proposed formulation to support that claim. Instead, the letter contained largely boiler-plate recitations of legal authority, with less than fifteen lines of information dedicated to any actual explanation of Mylan's proposed generic formulation.

In the ensuing weeks, in order to understand Mylan's proposed generic formulation, Sciele attempted to negotiate with Mylan to obtain access to ANDA No. 79-051 under 21 U.S.C. § 355(j)(5)(C)(i)(III), but Mylan refused to provide access except under very restrictive conditions. Accordingly, to protect its rights in Sular®, Sciele was forced to file suit on October 22, 2007 to comply with the statute's requirement that a lawsuit be filed within 45 days of receiving a Paragraph IV letter.

Just over two weeks later, on November 7, 2007, Sciele received a second Paragraph IV letter from Mylan, this time informing Sciele that Mylan had amended ANDA No. 79-051 to seek FDA approval to manufacture and sell generic versions of the 20mg and 30mg dosages of Sular® as well. Other than this difference, the letter was identical to the first letter, with almost no actual information regarding Mylan's proposed formulation. Like it did after receiving the first Paragraph IV letter, Sciele again tried to negotiate with Mylan regarding access to the ANDA, but Mylan again refused to budge from the unreasonable conditions that it had offered

the first time. Therefore, Sciele filed a second lawsuit on the amended ANDA on December 14, 2007, relating it to the first lawsuit as required by the Local Rules.

IV. ARGUMENT

A. Mylan's Motion to Dismiss Should Be Denied Because Sciele Has "All Substantial Rights" in the '741 Patent.

The Patent Act provides that a "patentee" is entitled to bring a civil action for "infringement of his patent." 35 U.S.C. § 281. The term "patentee" includes "not only the patentee to whom the patent was issued but also the successors in title to the patentee." 35 U.S.C. § 100(d).

Courts have interpreted these provisions of the Patent Act to allow a licensee to bring suit in its own name if the licensee holds "all substantial rights" under the patent. *Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.P.A.*, 944 F.2d 870, 875 (Fed. Cir. 1991) (finding licensee had standing to sue in its own name because agreement transferred all substantial rights to the licensee). A party that has been granted "all substantial rights" is considered the patentee regardless of how the parties characterize the transaction that conveyed those rights. *Id.* at 874-75; *see also Speedplay, Inc. v. Bebop, Inc.*, 211 F.3d 1245, 1250 (Fed. Cir. 2000).

In determining whether a license has the effect of conveying all substantial rights to the licensee, courts focus on both the "intention of the parties" as well as the "substance of what was granted." *Vaupel*, 944 F.2d at 874. Both factors demonstrate that Sciele has all substantial rights and is the appropriate plaintiff in this case.

1. The Parties Intended the Agreements to Transfer All Substantial Rights to Sciele.

Because analysis of the rights possessed by the parties in a patent license agreement is a matter of contract interpretation, *see Nicolson Pavement Co. v. Jenkins*, 81 U.S. (14 Wall.) 452,

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456 (1871), the Court must look to the intent of the parties. The Federal Circuit's standing jurisprudence has repeatedly emphasized the importance of that intent in determining the nature of a license in the "all substantial rights" analysis. *See Vaupel*, 944 F.2d at 874 ("To determine whether a provision in an agreement constitutes an assignment or a license, one must ascertain the intention of the parties and determine the substance of what was granted."); *see also Mentor H/S, Inc. v. Med. Device Alliance*, 240 F.3d 1016, 1017 (Fed. Cir. 2001) ("To determine whether an agreement constitutes just an exclusive license or instead also transfers 'all substantial rights' in a patent, we must ascertain the intention of the parties and examine the substance of what was granted by the agreement.").

Here, the intent of Bayer and Sciele is plain.

[Ex. B, 2007 Agreement at C.] To ensure that Sciele holds all substantial rights in the '741 Patent,

[*Id.* at Section 2.9.] By these provisions, the parties plainly intended that Sciele would be able to file actions for infringement of the '741 Patent on its own, without joining Bayer.

2. The Agreements Conveyed All Substantial Rights in the '741 Patent to Sciele.

Bayer and Sciele have effectuated their clear intent through the extensive rights Bayer granted to Sciele, both in 2007 and in 2004. Under the relevant authorities, these rights are "all substantial rights" needed for Sciele to stand on its own in enforcing the '741 Patent in this case.

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In determining whether a licensee enjoys "all substantial rights," courts have looked to four categories of rights that the patentee could grant to a licensee or retain for itself. These are: (1) the right to sue potential infringers or otherwise control enforcement of the patent for practical purposes; (2) the right to grant sublicenses to the patent; (3) the right to make, use and sell the patented invention; and (4) title to and the obligation to maintain the patent. *See Propat Int'l Corp v. RPost, Inc.*, 473 F.3d 1187, 1190-93 (Fed. Cir. 2007); *see also Speedplay*, 211 F.3d at 1250-52; *Vaupel*, 944 F.2d at 873-76.

In its motion, Mylan either: a) relies on outdated information as to these rights (nos. 1, 2 and 3); b) omits them completely (no. 2); or c) seriously mischaracterizes them or their importance to the standing analysis (nos. 1, 3 and 4). Under the appropriate analysis of the existing agreements, Bayer's retained rights are insubstantial and Sciele possesses all substantial rights. Sciele is therefore entitled to sue Mylan in its name alone.

a.

Control over the right to sue for infringement is an important factor in the standing analysis. *See Vaupel*, 944 F.2d at 875 (referring to the right to sue for infringement as "particularly dispositive" in determining that the exclusive licensee had standing to sue in its own name). This is the case because the main policy behind the rule that a licensee of less than all substantial rights must join the patentee is to prevent the risk of multiple lawsuits against the infringer for the same act of infringement. *See Crown Die & Tool Co. v. Nye Tool Mach. Works*, 261 U.S. 24, 38 (1923).

Plainly, there is no risk that Mylan will face an additional lawsuit under the '741 Patent from Bayer over Mylan's infringing act of having filed an ANDA for a generic version of Sular®. Indeed, Mylan does not even argue the point in its brief. And the actual agreements

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between Sciele and Bayer—as opposed to the superseded provisions argued by Mylan—demonstrate why.

In its motion, Mylan incorrectly relies on section 16.2 of the 2001 Agreement to argue that Bayer has retained a substantial right to sue infringers. That provision covers patent infringement litigation not stemming from a Paragraph IV letter and, in addition to being superseded, is not even relevant to this case.

[Ex. A, 2004 Agreement, Section 16.3; Ex. B, 2007 Agreement, Section 2.9.]

[*Id.*]

[*Id.* at 16.3.]

See Gould v. Control Laser Corp., 462 F. Supp. 685, 687 (M.D. Fla. 1978) (requiring *licensee* to be joined in infringement suit because patentee's "ownership so substantially limited in enjoyment is not in any realistic sense ownership at all" and licensee's "control over the … patent is so sweeping that it has become in economic reality the assignee of the patent").

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The Federal Circuit has recognized that

is rendered inconsequential by the division of rights in the rest of the agreements. In *Speedplay, Inc. v. Bebop, Inc.*, the Federal Circuit determined that an exclusive licensee had standing to sue in its own name despite the fact that the patentee retained a right to sue for infringement if the licensee did not do so within three months. *Speedplay*, 211 F.3d at 1251-52. The licensee had the exclusive right to make, use, and sell the patented product, as well as the right to grant sublicenses freely. *Id.* at 1250-51. The Federal Circuit determined that, based on the division of rights in the agreement, the patentee's retained right to sue was illusory because the licensee could "render that right nugatory by granting the alleged infringer a royalty-free sublicense." *Id.* at 1251. Thus, the court reasoned that the licensee "controls enforcement of the [patent-in-suit] for all practical purposes. Even though [the patentee] retained the right to sue, that right would not hinder [the licensee's] enjoyment of the patent rights in any meaningful way." *Id.*

Here, as in *Speedplay*, Sciele effectively controls enforcement

[Ex. B, 2007 Agreement, Section 2.6 (

').]

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b.

Mylan also wrongly argues that Sciele does not have the right to make Sular®. This argument, like Mylan's argument about Bayer's retention of some portion of the right to sue, is simply based on outdated information.

[Ex. B, 2007 Agreement,

It is difficult to see how these rights, are anything less than "all substantial rights." *See McNeilab, Inc. v. Scandipharm, Inc.*, No. 94-1508, at 1996 WL 431352 (Fed. Cir. July 31, 1996) (unpublished) (holding that licensee possessed "all substantial rights" where licensee had the exclusive right to make, use and sell pharmaceutical product covered by the patent and the right to enforce the patent).

c. Bayer's Retained Rights Are Not Substantial

Mylan's final two arguments about the supposedly substantial rights retained by Bayer—certain rights to develop new nisoldipine products as well as title to and the obligation to maintain the '741 Patent—hold up no better than the first two. First, Mylan wrongly argues that Bayer retains the right to develop and introduce new nisoldipine products under the '741 Patent and could theoretically offer patented products to third parties under certain circumstances. [D.I.

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13, at 14.] But, in fact, in the 2004 Agreement, Bayer simply retains the general right to develop new products using nisoldipine as the active ingredient, not the right "to develop and introduce new nisoldipine products *under the '741 patent*," as Mylan incorrectly characterizes it. [Ex. A, 2004 Agreement, Section 11.1; D.I. 13, at 14 (emphasis added).] The '741 Patent does not claim all nisoldipine-containing pharmaceutical products in general. The retained right argued by Mylan is not a retained right under the patent at all.

Mylan's final argument is that Bayer retains substantial rights because the 2001 Agreement refers to Bayer as the "sole and exclusive owner" of the patent and requires it to maintain the patent. [D.I. 13, at 13.] But, of course, if ownership settled the question, no exclusive licensee could ever bring suit for infringement on its own, as they do all the time, exactly as Sciele and Bayer envisioned. And while courts have referred to whether the patentee retains an obligation to maintain the patent as a factor to consider in determining whether all substantial rights have been granted, *see, e.g.*, *Mentor*, 240 F.3d at 1018, no case has ever found such an obligation dispositive.

Sciele holds all substantial rights in the '741 Patent and is entitled to bring suit in its own name. Mylan's motion to dismiss this case for lack of standing should be denied.

B. In the Alternative, Sciele Is Entitled to Sue Jointly With Bayer and the Remedy of Dismissal Is Inappropriate

Even if the Court finds that Sciele does not have all substantial rights in the '741 Patent—and it should not—Sciele is, at worst, an exclusive licensee and thus entitled to sue for

infringement jointly with Bayer. Accordingly, in the alternative, leave to amend to add Bayer as a plaintiff should be granted.

1. There Are Two Types of Standing Requirements and Three Types of Possible Plaintiffs in a Patent Infringement Suit

Patent infringement lawsuits implicate two types of standing concerns—Article III constitutional standing and statutory prudential standing. *Propat*, 473 F.3d at 1193. Article III or constitutional standing requires: (1) injury in fact—invasion of a legally protected interest which is concrete and particularized and actual or imminent; (2) a causal connection between the injury and the conduct complained of; and (3) a likelihood that the injury would be redressed by a favorable decision. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992). An injury to the statutorily granted right to exclude is injury in fact for purposes of Article III standing. *See Intellectual Prop. Dev. Corp. v. TCI Cablevision of Cal., Inc.*, 248 F.3d 1333, 1346-47 (Fed. Cir. 2001).

In addition to the Article III requirement, the standing doctrine embraces judicially self-imposed limits, known as "prudential limits," on the exercise of jurisdiction. *Id.* at 1348. These limits exist to avoid the possibility of multiple lawsuits against a party for the same act of infringement. *Vaupel*, 944 F.2d at 875.

Under these doctrines, there are three possible types of plaintiffs in a patent infringement suit: those that have both constitutional and prudential standing, those that have constitutional but lack prudential standing, and those that have no standing at all. Patentees and exclusive licensees with all substantial rights in a patent are in the first category and thus have the right to sue in their own name alone. *Intellectual Prop. Dev.*, 248 F.3d at 1345. Non-exclusive or "bare" licensees fall into the third category and have no right to sue for infringement, with or without the patentee. *Id.*

Exclusive licensees of less than all substantial rights fall into the second category. As exclusive licensees, they are injured by infringement and possess Article III standing, but because they lack all substantial rights, they must sue as a co-plaintiff with the patentee. *See id.* at 1346 ("A party such as IPD that has the right to exclude others from making, using, and selling an invention described in the claims of a patent is constitutionally injured by another entity that makes, uses, or sells the invention."); *Ortho Pharm. Corp. v. Genetics Institute, Inc.*, 52 F.3d 1026, 1031-32 (Fed. Cir. 1995) ("[I]t is the licensee's beneficial ownership of a right to prevent others from making, using, or selling the patented technology that provides that foundation for co-plaintiff standing.")

2. Where an Exclusive Licensee Has Less Than All Substantial Rights, the Proper Remedy is to Join the Patentee as a Co-Plaintiff, Not to Dismiss the Lawsuit

When a party has constitutional standing but merely lacks prudential standing, the remedy to cure the standing defect is not dismissal, but rather joinder of the absent owner. *Schreiber Foods, Inc. v. Beatrice Cheese, Inc.*, 402 F.3d 1198, 1203 n.4 (Fed. Cir. 2005). ("If the original plaintiff had Article III standing, any prudential standing concerns may be overcome by adding a plaintiff with proper standing."); *see also Intellectual Prop. Dev.*, 248 F.3d at 1348 (affirming district court's grant of leave to amend complaint to add patentee); *Abbott Laboratories v. Diamedix Corp.*, 47 F.3d 1128. 1130 (Fed. Cir 1995) (permitting patentee to intervene in licensee's suit rather than dismissing complaint); *Calgon Corp. v. Nalco Chem.*, 726 F. Supp. 983, 990 (D. Del. 1989) (finding that licensee did not have standing to sue in its own name but permitting amendment of complaint to add patentee as co-plaintiff).

Even the authority relied upon by Mylan demonstrates that joinder, not dismissal is the appropriate remedy to cure a standing defect. *See Mentor*, 240 F.3d 1016 (cited by Mylan at 16-17). In *Mentor*, the jury returned a verdict against the alleged infringer, who then successfully

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moved for JMOL and a new trial on a variety of issues. *Id.* at 1017. On appeal, the Federal Circuit *sua sponte* raised the standing issue and ruled that Mentor did not have standing to sue without its licensor as a party. *Id.* Upon Mentor's motion, the Federal Circuit then allowed the joinder of the licensor *during the appeal* after finding that there would be no prejudice to the defendant. *See Mentor H/S, Inc. v. Medical Device Alliance, Inc.*, 244 F.3d 1365, 1373 (Fed. Cir. 2001).

3. Because Sciele is an Exclusive Licensee, the Proper Remedy is Joinder of Bayer

Under these authorities, there can be no dispute that Sciele is an exclusive licensee and therefore possesses constitutional standing. Sciele has the

[Ex. B, 2007 Agreement, Section 2.6.]

Id. Mylan's proposed generic copy of Sular® threatens these exclusive rights of Sciele, and gives rise to constitutional standing (as well as prudential standing, as demonstrated above).

But, if despite the broad transfer of rights to Sciele from Bayer, and the clear intent of the parties as reflected in the 2007 Agreement, the Court finds that Sciele does not possess "all substantial rights," the proper remedy is joinder of Bayer as a co-plaintiff, as demonstrated above, and not dismissal, as requested by Mylan. Obviously, if joinder after a jury verdict and during an appeal is appropriate, *see Mentor*, 244 F.3d at 1373, joinder at the pleadings stage in the district court is appropriate, as well.

In its motion, Mylan does not even address this well-settled law, choosing instead to rely on *Textile Productions, Inc. v. Mead Corp.*, 134 F.3d 1481 (Fed. Cir. 1998), in its desire for dismissal at any cost. *Textile Productions*, however, is inapposite because, in that case, the

licensee did not possess the *exclusive* rights to make, use, and sell under the patent, the *exclusive* right to sublicense its rights to others, or the right to file suit against infringers and collect damages. *Id.* at 1483-85. Sciele, on the other hand, has all these rights.

Textile Productions thus presents a far different fact pattern than this case, in which Sciele's rights are exclusive and Bayer cannot license them to others. Sciele therefore requests that, if the Court finds that Sciele alone lacks prudential standing, the Court grant Sciele's conditional Motion to Amend its Complaint to join Bayer as a co-plaintiff rather than dismissing the case.[6] [Marsden Decl., Ex. C, Motion for Leave to File Amended Complaint.] Mylan would not be prejudiced at this early stage of the case, where discovery has not yet commenced. And while Sciele can only speculate as to why Mylan asks for dismissal instead of Bayer's joinder—perhaps simply to attack Sciele's statutorily-granted stay on FDA approval of Mylan's ANDA—it is clear that it would be error to dismiss this case under the very Federal Circuit authority cited by Mylan. Together, Sciele and Bayer meet the constitutional and prudential standing requirements, and, if necessary, the Court should grant Sciele's provisional leave to amend, thereby allowing Sciele the opportunity to litigate this dispute in the fashion envisioned by the Hatch-Waxman Act, without Mylan prematurely destroying the market for Sular® that Sciele has worked so hard to create.

V. CONCLUSION

Sciele respectfully requests that the Court deny Mylan's motion to dismiss and allow Sciele, the exclusive licensee of all substantial rights in the '741 Patent, to proceed with this suit in its own name. In the alternative, if the Court finds that Sciele is an exclusive licensee of less

[6] Leave to amend under Federal Rule of Civil Procedure 15 is to be freely granted. *See* Fed. R. Civ. P. 15; *Blasband v. Rales*, 971 F.2d 1034, 1055 (3d Cir 1992).

than all substantial rights, Sciele requests that the Court allow Sciele to join Bayer as a co-plaintiff rather than dismiss the case.

Dated: January 28, 2008

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CERTIFICATE OF SERVICE

I hereby certify that on January 28, 2008, I electronically filed with the Clerk of Court **PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS PLAINTIFFS' COMPLAINT FOR LACK OF STANDING AND SUBJECT MATTER JURISDICTION** using CM/ECF which will send electronic notification of such filing(s) to the following Delaware counsel. In addition, the filing will also be sent via hand delivery:

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I also certify that on January 28, 2008, I have sent by electronic mail and U.S. First Class Mail, the document(s) to the following non-registered participants:

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